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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/955,248	09/17/2001	Leo Martis	DI-4641 CONT	8992

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[REDACTED] EXAMINER

KEYS, ROSALYND ANN

ART UNIT	PAPER NUMBER
1621	

DATE MAILED: 01/30/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/955,248	MARTIS ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Rosalyn Keys	1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-16 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-16 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.
 

If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All
  - b) Some \*
  - c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
  - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                    | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### ***Status of Claims***

1. Claims 1-16 are pending.

Claims 1-16 are rejected.

### ***Claim Objections***

2. Claims 6, 10 and 11 are objected to because of the following informalities:  
certain concentrations of the various components of the dialysis solutions are incomplete, i.e., the Bicarbonate concentration is disclosed as 20.0-30., whereas it should be 20.0-30.0. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Veech (US 4,663,166) or Veech (US 6,020,007) in view of Zander (US 5,296,242).

Veech '166 teaches the claimed invention at column 14, line 53 to column 16, line 37; column 31, lines 13-18; column 40, line 42 to column 42, line 16; and column 65, lines 29-48.

Veech '007 teaches the claimed invention at column 3, line 53 to column 9, line 55.

Veech '166 and Veech '007 each fail to disclose the CO<sub>2</sub> partial pressure of the peritoneal dialysis solution.

Zander discloses that preliminary research revealed that dialysis solutions are particularly suitable if their pH-value, bicarbonate concentration and CO<sub>2</sub> partial pressure correspond to the physiological blood plasma values (see column 2, lines 35-39). These physiological values are for pH value 7.40+/-0.05, for the bicarbonate

concentration 24 mmole/l and for the CO<sub>2</sub> partial pressure 40 mmHg (see column 2, lines 40-43).

One having ordinary skill in the art at the time the invention was made would have been motivated to use a CO<sub>2</sub> partial pressure which corresponds to the physiological blood plasma values, i.e. 40 mmHg as taught by Zander, for the peritoneal dialysis solution of either Veech '166 or Veech '007, since Zander discloses that the use of such solutions would ensure that there is not overdosing or underdosing relative to the acid-base status and consequently an alkalosis or acidosis is produced, that no hyperventilation or hypoventilation occurs with respect to the breathing of a patient or that there are no local reactions on the peritoneum when used as a peritoneal dialysis solution (see column 2, lines 43-54).

7. Claims 1-5 are rejected under 35 U.S.C. § 103 as being unpatentable over Schambye et al. (International Society of Peritoneal Dialysis) in view of Zander (US 5,296,242).

Schambye et al. discloses peritoneal dialysis solutions having bicarbonate concentrations of 10-20mM, lactate concentrations of 20.8-6.7 mM and pH's of 7.0-7.4. A solution with a bicarbonate concentration of 20mM, a lactate concentration of 12.5 mM and a pH of approximately 7.2 being the least cytotoxic (see page S116, abstract and page S118).

Schambye et al. fails to specifically disclose CO<sub>2</sub> partial pressures of the peritoneal dialysis solution however, Schambye et al. discloses that all the examinations were carried out in a 40 mmHg CO<sub>2</sub> atmosphere.

Zander discloses that preliminary research revealed that dialysis solutions are particularly suitable if their pH-value, bicarbonate concentration and CO<sub>2</sub> partial pressure correspond to the physiological blood plasma values (see column 2, lines 35-39). These physiological values are for pH value 7.40+/-0.05, for the bicarbonate concentration 24 mmole/l and for the CO<sub>2</sub> partial pressure 40 mmHg (see column 2, lines 40-43).

One having ordinary skill in the art at the time the invention was made would have been motivated to use a CO<sub>2</sub> partial pressure which corresponds to the physiological blood plasma values, i.e. 40 mmHg as taught by Zander, for the peritoneal dialysis solution of Schambye et al. since Zander discloses that the use of such solutions would ensure that there is not overdosing or underdosing relative to the acid-base status and consequently an alkalosis or acidosis is produced, that no hyperventilation or hypoventilation occurs with respect to the breathing of a patient or that there are no local reactions on the peritoneum when used as a peritoneal dialysis solution (see column 2, lines 43-54).

### ***Double Patenting***

8. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to

identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

9. Claims 1-16 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1, 2, 4-6, 8-10, 12-14, and 16-20 of copending Application No. 08/421,020. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

#### ***Information Disclosure Statement***

10. The information disclosure statement filed September 17, 2001 has been considered except for the reference which are lined through. Certain references were lined through because a copy of the reference was not supplied.

#### ***Conclusion***

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Veech (US 5,100,677) disclose a solution useful in the treatment of acidosis (see column 7, line 42 to column 10, line 32.

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12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosalynd Keys whose telephone number is 703-308-4633. The examiner can normally be reached on M-F 5:30 a.m.-10:30 a.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 703-308-4532. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

  
Rosalynd Keys  
Primary Examiner  
Art Unit 1621

  
R. Keys  
January 25, 2002